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SECTION 17: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

17.1 SUBMITTER INFORMATION

a. Company Name:	FRIADENT GmbH.
b. Company Address:	Steinzeugstrasse 50 Mannheim D-68229 Germany
c. Company Phone: Company Facsimile:	(011) 49 621 43 02 1121 (011) 49 621 43 02 2121
d. Contact Person:	Heike Dietzler Regulatory Affairs Manager
e. Date Summary Prepared:	September 15, 2003

17.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	XiVE® 3.0 Dental Implant System
b. Classification Name:	Endosseous Dental Implants 21 CFR 872.3640

17.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
FRIADENT GmbH	XiVE® 3.0 Dental Implant System	K030639	08/12/2003

17.4 DEVICE DESCRIPTION

The XiVE® 3.0 Dental Implant System consists of subgingival threaded dental implants with 11 – 15mm lengths. The implants are coated with the FRIADENT

Surface M2.1. The XiVE® 3.0 Dental Implant System is comprised of dental implants, surgical and laboratory instruments and prosthetic components. The system is designed for single tooth and splinted tooth restorations in the anterior regions of the mouth.

17.5 SUBSTANTIAL EQUIVALENCE

The XiVE® 3.0 dental implants with the FRIADENT Surface M2.1 are substantially equivalent to the current XiVE® 3.0 Dental Implant Systems in terms of design, materials, mechanical strength, prosthetic and laboratory options and intended use.

17.6INTENDED USE

The XiVE® 3.0 Dental Implant System is indicated for single tooth restorations and splinted tooth restorations in the region of 7 to 10 and 23 to 26.

17.7 TECHNOLOGICAL CHARACTERISTICS

The XiVE® 3.0 dental implant is available in screw-type subgingival implants with the FRIADENT Surface M2.1. The lengths of the implants range from 11 – 15mm. The XiVE® 3.0 dental implants are constructed of CP-2 titanium. A variety of prosthetic options are available for the XiVE® 3.0 system including, AuroBase, EstheticBase, Telescopic, and Select Abutments.

The XiVE® 3.0 dental implants with the FRIADENT Surface M2.1 is equivalent to the current XiVE® 3.0 Dental Implant System in terms of design, materials, mechanical strength, prosthetic options, instructions for use and intended use. The only difference is the change in the surface morphology of the dental implant to the FRIADENT Surface M2.1.

17.8 CLASS III CERTIFICATION AND SUMMARY

This notification contains a Class III certification and summary of adverse safety and effectiveness information pursuant to 513(f) of the Federal Food, Drug, and Cosmetic Act.

17.9 CONCLUSIONS

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer=s Checklist is provided in this submission. Performance evaluations of the XiVE® 3.0 dental implant system show that the device performs as intended. Comparisons of the XiVE® 3.0 dental implants to the predicate devices show that the device is substantially equivalent. The complete surface characterization of the new FRIADENT Surface M2.1 has been detailed in a Device Master File.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Patterson Consulting Group, Incorporated
C/O Ms. Carol Patterson
Friadent GmbH
21911 Erie Lane
Lake Forest, California, 92630

Re: K032750
Trade/Device Name: XiVE® 3.0 Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implants
Regulatory Class: III
Product Code: DZE
Dated: September 3, 2003
Received: September 5, 2003

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed,predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032750

INDICATION FOR USE

510(k) Number:

Device Name: XiVE® 3.0 Dental Implant System

Indications for Use: The XiVE® 3.0 Dental Implant System is indicated for single tooth restorations and splinted tooth restorations in the region of 7 to 10 and 23 to 26.

Kevin Mulley for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032750

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)